

Non-State Entity Application: VHCURES Limited Use Health Care Claims Research Data Set

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APPLICATION INSTRUCTIONS

Introduction

The Vermont Health Care Uniform Reporting and Evaluation System (VHCURES)

The Vermont legislature authorized the collection of eligibility and claims data for Vermont residents to enable the Green Mountain Care Board (GMCB) to carry out its statutory duties that include determining the capacity and distribution of existing resources; identifying health care needs and informing health care policy; evaluating the effectiveness of intervention programs on improving patient outcomes; comparing costs between various treatment settings and approaches; providing information to consumers and purchasers of health care; and improving the quality and affordability of patient health care and health care coverage. (18 V.S.A. § 9410)

The GMCB is required to make the VHCURES data set available as a resource for individuals and entities to continuously review health care utilization, expenditures, and performance in Vermont to the extent permitted by the Health Information Portability and Accountability Act (HIPAA) and other pertinent state and federal laws.

The claims and eligibility data available under a data use agreement can be broadly grouped into three lines of business including commercial, Medicaid, and Medicare. The GMCB has independent discretion to make decisions regarding the use and disclosure of commercial insurer data. The Department of Vermont Health Access (DVHA) and the GMCB share discretion with respect to the Medicaid data subset. DVHA must approve the use and disclosure of Medicaid data and must sign the Data Use Agreement (DUA) for authorized users of the Medicaid data subset. Per an agreement with the federal Centers for Medicare and Medicaid Services (CMS), the Medicare data subset is available only to Vermont State Agencies and entities performing research that is directed and partially funded by the State of Vermont. Under a DUA between GMCB and CMS, GMCB has independent discretion to make decisions regarding the use and disclosure of the Medicare data subset by Vermont state agencies.

Vermont state agencies may apply for a standard comprehensive research data set that includes all unrestricted and restricted data elements for broad use internally and by state contractors. Non-state entities may apply for a DUA for a limited use health care claims research data set using a different application form. This type of data set excludes the Medicare data subset and is tailored to specific research purposes as approved by GMCB and DVHA if the Medicaid data subset is requested. Applicants who are non-state entities must justify requests for individual restricted data elements and explain how the requested restricted data elements are applicable to the intended research purpose.

Data Governance Council

The GMCB chartered the [Data Governance Council](#) (DGC) to oversee the stewardship of VHCURES including the development and revision of principles and policies to guide decisions on data use and disclosure. The DGC supports the GMCB decision-making process for applications requesting use and disclosure of VHCURES data sets by non-state entities as addressed in this application form.

Application Review Process

This application is required of non-state entities requesting a DUA for a VHCURES limited use health care claims research data set (hereafter referred to as a limited use research data set) with the option of including the commercial and Medicaid data subsets to support a project focused on a specific research purpose or study.

GMCB staff must deem this application complete before initiating the full review process. **This includes submission of all required and applicable optional attachments as listed in the Application Checklist in this application.** Applicants must include a full list of individuals who will have access to the data set upon the effective date of the DUA with this application. Applicants must file Individual User Affidavits (IUA) signed by the Authorized User (AU) or Principal Investigator (PI) for all data users listed on this application. AUs or PIs must ensure that IUAs are filed with GMCB for future data users prior to their access to the data set or risk forfeiture of the DUA and the data set.

After an application is deemed complete, GMCB will start the application review process that may include a public discussion of the application by the DGC. The GMCB has the discretion to approve or disapprove applications for a DUA. All requests for the Medicaid data subset must also be approved by the Department of Vermont Health Access (DVHA). The GMCB will provide DVHA with a copy of the complete application, following a review of the application by the GMCB. Applicants may also be required to obtain approval of the AHS Institutional Review Board (IRB) Committee. (See <http://humanservices.vermont.gov/boards-committees/irb>)

The Agency of Administration (AOA) under "Procurement and Contracting Procedures" of Bulletin 3.5 is required to review and approve the DUA after the GMCB and DVHA, if applicable, have approved the application for a DUA.

The GMCB must review and approve requests by non-state entities to re-disclose data including custom extracts to contractors, subcontractors, or other external entities. Non-state entities must file project review forms (PRF) with the GMCB prior to re-disclosing the data set or any extracts generated from the data set to any external entities. This ensures continued compliance with provisions of state and federal laws and regulations. The GMCB must also review any proposal to change the use or research purpose of the data after the DUA has been issued for a specific research purpose that is different. The requestor must file a Request for Change in Use Form (RCUF). The GMCB may require the filing of an application for a new DUA after reviewing the RCUF.

Final Steps in the Application Process

If approved by AOA, the GMCB and the applicant jointly enter into a DUA that is signed by the Authorized User, Principal Investigator, GMCB, and DVHA if the Medicaid data subset is included. Prior to receiving the data set approved under the DUA, all individuals accessing and using the data on behalf of the Authorized User must sign IUAs attesting to understanding the appropriate use and disclosure of the data set and agree to comply with the requirements. If GMCB declines an application, a written statement identifying the specific basis for denial of the application will be provided to the applicant. The applicant may resubmit or supplement the application to address GMCB's concerns including those

of DVHA if Medicaid data are being requested. An adverse decision regarding an application may be appealed to the GMCB.

General Instructions

Applicants must complete all required sections of the application and submit an electronic copy of the completed application, including all attachments, to Dian.Kahn@vermont.gov. Incomplete applications will not be reviewed until the applicant has provided all required information. An application checklist is provided to help ensure that your application is complete. For questions about the application process, Dian.Kahn@vermont.gov

Definitions

Agent: Means any individual or entity (e.g., a contractor, subcontractor, grantee, or subgrantee) acting on behalf of the Authorized User and subject to the Authorized User's control or accessing the Data Set on behalf of the Authorized User.

Authorized User: The Authorized User (AU) is typically an organization or agency. The AU signatory to the Application and the DUA must have the authority to sign legally binding agreements on behalf of the organization or institution.

Custom Extract: A custom extract includes the minimum necessary data to support the research purpose. A custom extract is a data subset or table generated from the commercial and Medicaid data subsets. The Medicare data subset is only available to Vermont state agencies under the data use agreement between CMS and the GMCB.

This process ensures continued compliance with the requirements of the DUA and particularly supports the concept of using the minimum necessary data to support the approved research purpose. For example, if the study approved under a VHCURES DUA addresses pediatric asthma in the Medicaid population, the GMCB may approve use of a custom extract that includes Medicaid paid claims data for enrollees under the age of 19 only.

Data Custodian: The data custodian is responsible for the establishment and maintenance of physical and technical safeguards to prevent unauthorized access to and use of the data set. Agencies may designate multiple data custodians for different departments and programs. The data custodian(s) typically coordinate the receipt of the approved data set from GMCB's data consolidation vendor. The principal investigator may also be the data custodian. State contractors or other agents approved by the GMCB through a Project Review to receive the data set or custom extracts must identify and file contact information for their data custodian(s) with the GMCB.

Institutional Review Board (IRB): An institutional review board (IRB), also known as an independent ethics committee (IEC), ethical review board (ERB), or research ethics board (REB), is a committee that

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has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans.

Principal Investigator (PI): The Principal Investigator means the individual designated by the Authorized User to be responsible for ensuring compliance with all the restrictions, limitations, and conditions of use and disclosure specified in the DUA. The Principal Investigator may delegate technical responsibility to other personnel for the establishment and maintenance of security arrangements to prevent unauthorized access to and use of the data.

Project Review: Any entity with a VHCURES DUA intending to re-disclose the VHCURES data set or any custom extracts of the data set to external agents including contractors, subcontractors, and any other external parties must file a Project Review Form (PRF) with the GMCB for review and approval prior to the re-disclosure.

After the GMCB has reviewed a Project Review Form (CPRF) and approved re-disclosure of data to an external agent, the entity holding the DUA may generate custom data extracts or obtain extracts from the GMCB data consolidation vendor. As needed, the GMCB may request its data consolidation vendor to generate custom data extracts for the contractor or allow the approved entities to access the secured data enclave hosted by the vendor. Use of services provided by the GMCB's data consolidation vendor may require payment of a fee to the vendor. This will be determined by GMCB a case-by-case basis.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

State Entity: Vermont state agencies, contractors, or other external agents performing work for the State of Vermont. A non-state entity is not a Vermont state agency or an agent performing work directed and funded by the State of Vermont.

Application Checklist (For use by the applicant. Applicants must include all required attachments and applicable optional attachments)

Completed Application

- ☐ **Section 1:** Research Summary
- ☐ **Section 2:** Data Management Plan
- ☐ **Section 3:** Project Team (*Including data users for whom signed IUAs are being filed*)
- ☐ **Section 4:** Data Procurement and Price
- ☐ **Section 5:** Data Transmission and Receipt
- ☐ **Section 6:** Signatures

Required Attachments

- ☐ **Attachment 1:** Signed Data Use Agreement (*Must be signed by the Authorized User and Principal Investigator*)
- ☐ **Attachment 2:** Entity's Data Governance and Protection Policies and Procedures
- ☐ **Attachment 3:** Limited Use Research File Specification (Includes justification for requesting restricted data elements as necessary to support the specific research purpose)

Optional Attachments Applicable to Proposed Re-Disclosures of the Data or Extracts

- ☐ **Attachment 4:** Copy of proposed contracts, subcontracts, or any other agreements with external agents requiring re-disclosure of the data set or custom extracts
- ☐ **Attachment 5:** Project Review Form(s) (PRF) must be filed for every external agent identified under Attachment 4 to whom the data or data extracts will be re-disclosed by the entity in possession of the DUA
- ☐ **Attachment 6:** Data Governance Policies and Procedures for every external agent identified under Attachment 4 that will be receiving and managing the data set or extracts of the data set

Miscellaneous Optional Attachments

- ☐ **Attachment 7:** If applicable to this application, IRB review and approval document
- ☐ **Attachment 8:** Other materials requested by the GMCB for the purpose of reviewing the application

APPLICATION

Section 1: Research Summary

Section 1 summarizes the specific research purpose of the project requiring access to a limited use health claims research data set during the term of the DUA. The Authorized User must file a Request for Change in Use Form (RCUF) with the GMCB to propose any changes in the research purpose that are not specified in this application. The GMCB may require the filing of an application for a new DUA after reviewing the RCUF.

Answer every question in this section. If a question does not apply to your research project, indicate that the item is "Not Applicable." Do not leave a question blank or the application will be deemed incomplete.

1-1. Project Overview

Authorized User Signatory Name & Title: <i>Tony Dawson, Supply Chain Specialist</i>	
Organization/Entity Name: <i>RTI International</i>	
Type of Organization	<input type="checkbox"/> Federal or State government entity outside of Vermont <input type="checkbox"/> Contractor of Federal or State government entity outside of Vermont* <input type="checkbox"/> Academic Institution <input checked="" type="checkbox"/> Non-profit research organization <input type="checkbox"/> Participant in the Vermont health care system financing, insurance, or delivery system with direct impacts on the Vermont population <input type="checkbox"/> Participant in health care financing, insurance or delivery systems outside of Vermont <input type="checkbox"/> Health care enterprise such as manufacturers or distributors of pharmaceuticals and medical technology; designers and developers of health systems and facilities, etc. <input type="checkbox"/> Other: Please describe below
Principal Investigator Name & Title (if different from Authorized User): <i>Susan Haber, Director, Program on Health Coverage for Low-Income and Uninsured Populations</i>	
Project Name (Specify a topic or study): <i>Treatment and Outcomes for Patients with Opioid Use Disorder after Cessation of Opioid Prescriptions</i>	

Brief Project Description (Summary of subsection 1-5-1):

Despite efforts to reduce inappropriate prescriptions of opioid medications and expand opioid use disorder (OUD) treatment, opioid-related deaths continue to rise at an alarming rate. With increased use of Prescription Drug Monitoring Programs (PDMPs) and intensive focus on the opioid epidemic, physicians have become much more reluctant to continue prescribing large quantities and doses of prescription opioids. However, it is not clear what happens to individuals who are “cut off” from prescription opioids obtained through physician offices. Even though OUD treatment access is expanding and treatment is strongly associated with reduced risk of death, too few individuals with OUD initiate treatment, and among those who do initiate treatment, most individuals do not stay engaged in treatment. This study will analyze utilization patterns of individuals who are misusing/abusing prescription opioids and then are no longer filling opioid prescriptions to answer the following questions:

- 1. What factors are associated with OUD treatment initiation for patients who exhibit patterns of abusive fills of prescription opioids after physicians stop refilling their prescriptions?*
- 2. What factors are associated with longer engagement in OUD treatment for patients who initiate treatment?*

The first aspect of this study examines potential barriers to OUD treatment initiation, while the second aspect examines potential barriers to treatment engagement among individuals who do initiate treatment. The analysis will be conducted for individuals with Medicaid and private insurance because treatment patterns, the availability of services, and barriers to care may differ for those two insurance populations.

Project Start Date: 10/1/17

Project End Date: 9/30/18

Funding Source(s)

☐ State ☐ Federal ☒ If Other, please describe:

Internally funded by RTI International.

Line of Business data subset included in data request:

☒ Commercial ☒ Medicaid (DVHA must approve Medicaid data use)

If you intend to re-disclose the data to subcontractor(s) or other external parties, identify parties (Must align with documents filed under Attachment 4): *N/A. The RTI research team will not re-disclose the data to any subcontractors or external parties.*

1-2. Authorized User Acknowledgements

Please initial each item indicating your acknowledgement

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<i>TD</i>	<i>I agree that I have the authority to sign legally binding agreements on behalf of the organization or institution as applicable to this application and the attached Data Use Agreement (DUA).</i>
<i>TD</i>	<i>I have read and agree to the terms of the attached DUA. I understand the contents of the attached DUA may only be modified or amended in writing upon mutual agreement of both parties.</i>
<i>TD</i>	<i>I have read and agree to cooperate with the GMCB to amend the DUA from time to time to the extent necessary for the GMCB to comply with changes to 18 V.S.A. § 9410, HIPAA, or other legal requirements that may apply to the Data Set.</i>
<i>TD</i>	<i>I understand and agree that I am required to file signed Individual User Affidavits (IUAs) with the GMCB for every individual data user within my organization and those employed by any contractors, subcontractors or organizations outside my organization approved by the GMCB to access and use the VHCURES data set. I must file the IUAs prior to receipt of the data set and as new users join the project or risk forfeiture of the data set and the DUA.</i>
<i>TD</i>	<i>I understand and agree that I must obtain the express written approval of the GMCB to release the data set or any derived extracts of the data to any agents or parties outside my organization. I must file a Project Review Form (PRF) with the GMCB for review prior to any re-disclosure of the data set to parties outside of my organization or risk forfeiture of the data, the DUA and be subject to civil and criminal sanctions and penalties for an unauthorized disclosure of data.</i>

1-3. Project Questions

Answer the following questions about your research project.

Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Is the project directed by the State of Vermont including a Vermont state agencies and UVM?
Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Is this project partially or wholly funded by the State of Vermont?
Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Will products generated from the project be used for a proprietary, commercial purpose to generate revenues and income? If yes, explain below:
Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Is the project useful for determining the capacity and distribution of existing health care resources?
Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Is the project useful for identifying health care needs and informing health care policy?
Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Is the project useful for evaluating the effectiveness of intervention programs on improving patient outcomes?
Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Is the project useful for comparing costs between various treatment settings and approaches?
Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Is this project useful for providing information to consumers and purchasers of health care?
Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Is this project useful for improving the quality and affordability of patient health care and health care coverage?
Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Does the project directly support public health activities?
Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Does this project support educational purposes such as exploring the claims data for quality, potential uses, health services research training, or integration with other data sets?
Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Does this project propose to link VHCURES data with any other individual record-level data sets? <i>If yes, describe the data sets and proposed methodology for linking in Section 1-5-4.</i>
Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Does this project anticipate re-disclosure of the data set, custom extracts or analytical files generated from the data set to any identifiable external agents under contracts, grants, and agreements for research purposes that have been specified? <i>If yes, complete and file Attachment 4 and Attachment 5: Project Review Form.</i>

1-4. Requested Data

Indicate the data files requested in this application.

File Type	Commercial Insurers	Medicaid ¹	Medicare ²	Data Years or Date Range ³
Medical Eligibility-VT Residents	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Not applicable	Most recent 5 years

Medical Claims-VT Residents	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Not applicable	Most recent 5 years
Medical Eligibility- 5% National Sample	Not applicable	Not applicable	Not applicable	
Medical Claims- 5% National Sample	Not applicable	Not applicable	Not applicable	
Pharmacy Eligibility	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Not applicable	Most recent 5 years
Pharmacy Claims	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Not applicable	Most recent 5 years
Medicare Part D Event - VT Residents	Not applicable	Not applicable	Not applicable	
Medicare Part D Event - 5% National Sample	Not applicable	Not applicable	Not applicable	
Medicare MEDPAR	Not applicable	Not applicable	Not applicable	

¹ The Department of Vermont Health Access (DVHA) must approve uses and disclosure of Medicaid data.

² Medicare data may only be used for research directed and partially funded by the state of Vermont.

³ VHCURES data are available on a consolidated CY quarterly or annual basis on paid claims date basis starting with CY 2007.

1-5. Project Overview

1-5-1. Summarize the purpose and objectives of the proposed research. Describe how the research will contribute to generalizable knowledge applicable to the Vermont population, health, and health care and, if applicable, to the State of Vermont supporting the development, implementation, and evaluation of programs administered by Vermont state agencies.

Despite efforts to reduce inappropriate prescriptions of opioid medications and expand opioid use disorder (OUD) treatment, opioid-related deaths continue to rise at an alarming rate. With increased use of Prescription Drug Monitoring Programs (PDMPs) and intensive focus on the opioid epidemic, physicians have become much more reluctant to continue prescribing large quantities and doses of prescription opioids. However, it is not clear what happens to individuals who are “cut off” from prescription opioids obtained through physician offices. Even though OUD treatment access is expanding and treatment engagement is strongly associated with reduced risk of death, most individuals are not staying engaged in treatment.

This study will examine what happens to patients who have filled prescription opioids at levels indicative of misuse/abuse after physicians no longer fill their prescriptions. The study has two purposes: (1) to identify barriers to OUD treatment initiation; and (2) to identify factors that might be leveraged to increase engagement in OUD treatment.

The study population will include individuals with Medicaid and private insurance who fill opioid prescriptions in a manner indicative of misuse/abuse (indicated by the Pharmacy Quality Alliance measure) and then stop filling prescriptions. Medicaid and private insurance data will be analyzed separately because

treatment patterns, the availability of services, and barriers to care may differ for those two populations. We will conduct two sets of analyses for each population.

The first set of analyses will examine utilization patterns of individuals who are misusing/abusing prescription opioids and then are no longer filling opioid prescriptions to examine the following outcomes:

- *To what extent do these individuals transition to OUD treatment?*
- *To what extent do they transition to treatment at pain clinics?*
- *To what extent do they transition to using illicit opioids and overdose?*
- *To what extent do they have no obvious negative consequences?*

We will also examine factors associated with differing outcomes, including patient characteristics and the point of care in which prescription opioids are no longer filled.

The second set of analyses will focus on individuals who initiate OUD treatment to examine length of OUD treatment engagement and factors associated with longer engagement, including:

- *Receipt of treatment that is consistent with recommended guidelines*
- *Patient characteristics*
- *Provider characteristics*
- *Insurance characteristics*

Despite leading the country in efforts to expand access to opioid use disorder treatment and to reduce opioid prescribing, opioid overdose deaths involving prescription and non-prescription opioids continue to rise in Vermont, as they do in many other states. Although trending upward, engagement in treatment in Vermont, as in all other states, still hovers below 20 percent. These statistics highlight the critical need for greater efforts to identify ways to transition individuals in need into treatment and to retain them in treatment. These analyses will help meet this goal. The results will inform opioid treatment and policy and be of interest to the State of Vermont, providers, payers, and stakeholders, as well as federal agencies (SAMHSA, HRSA, CMS, ONDCP, NIH).

- 1-5-2. Summarize the credentials, skills, and experience of the Principal Investigator and key research staff that are evidence that the Data Set will be used to conduct and support systematic investigations guided by expertise in the subject matter and research methods, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

*The Principal Investigator, **Susan Haber, ScD**, has more than 25 years of experience conducting quantitative analyses of health insurance claims data for program and policy assessment and evaluation. Much of her work has focused on evaluations of Medicaid and, more recently, multi-payer initiatives. She has served as the project director or task leader of major components of many large studies funded by a variety of federal agencies including the Centers for Medicare and Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), the Agency for Healthcare Research and Quality (AHRQ), the Medicaid and CHIP Payment and Access Commission (MACPAC), and the Assistant Secretary for Planning and Evaluation (ASPE). Dr. Haber has extensive experience analyzing health insurance claims data obtained from a variety of sources, including CMS and individual states. She was Associate Project Director of the CMS-funded evaluation of the Multi-Payer Advanced Primary Care Practice (MAPCP) Demonstration, which used VHCURES data to assess the impact of the Vermont Blueprint for Health on Medicaid recipients. She currently directs an evaluation of Maryland's hospital global budget payment system that incorporates claims data from the state's APCD, among other sources.*

Jennifer Popovic, DVM, MA, is the director of the Program for Health Data and Standardized Methods within the Center for Health Data Analytics, where she designs and implements analytic infrastructure-building strategies, including evaluating the use of common data models and standardized analytic approaches and tools across healthcare-related projects. Her subject matter expertise is in the secondary use of real world data (RWD)—claims, disease registry, electronic health/medical record (EHR/EMR)—to inform population and public health studies, and is specifically focused on frameworks and methods of curating, structuring, linking, analyzing, and sharing health care data from disparate sources without sacrificing data integrity or patient privacy. Her analytic design approaches have contributed to the advancement of knowledge across several clinical content areas, including opioid prescribing patterns and use. As a scientific advisor to an FDA Sentinel-funded study to analyze opioid prescribing patterns in a commercially-insured population, Dr. Popovic was responsible for designing a tool to operationalize an opioid tolerance metric that characterized the proportion of patients who were dispensed an extended-release/long-acting (ER/LA) opioid analgesic with or without demonstration of prior opioid tolerance. The study underscored the potential need for better prescriber education regarding ER/LA opioid analgesics.

Tami L. Mark, PhD, is an internationally known health economist and expert on behavioral health care financing and delivery. Over the course of her 30-year career, Dr. Mark has led numerous projects for Federal agencies and has also consulted with state governments to improve their substance abuse treatment systems. Dr. Mark has extensive experience analyzing insurance claims data to provide insights into addiction treatment capacity, financing, and efficiency. She is widely published and was a contributing author to the Surgeon General's Report: Facing Addiction in America. Before joining RTI in 2017, Dr. Mark was a vice president and Director of the Center for Behavioral Health Services Research at Truven Health Analytics, an IBM company, previously known as Thomson Reuters and Medstat. Dr. Mark received her PhD from Johns Hopkins School of Public Health with support through an NIMH fellowship, her MBA from Loyola College, and her BA from Amherst College.

Alexander Cowell, PhD, is a senior research economist with expertise in the areas of substance use and mental health. In ongoing work, Dr. Cowell is directing a Robert Wood Johnson Foundation grant assessing plan coverage in Medicaid and in marketplace private plans for both SUD and mental health treatment. He is overseeing efforts to locate and abstract plan information from both types of insurance. Dr. Cowell also recently contributed to a project that assessed the impact of the 2014 Medicaid expansion on availability of SUD and mental health treatment, funded by the Office of the Assistant Secretary for Planning and Evaluation (ASPE). He was responsible for selecting relevant stakeholders, conducting discussions with them, and synthesizing the responses. Dr. Cowell is also a recognized expert in Screening and Brief Intervention for harmful alcohol/drug use and directs the federal Substance Abuse and Mental Health Administration's (SAMHSA's) cross-site evaluation of the Screening, Brief Intervention, and Referral to Treatment program. His portfolio also includes having led the economic component of an evaluation of SAMHSA's homeless programs and numerous economic evaluations of criminal justice interventions. Dr. Cowell's publication record includes journals such as *Addiction*, *Psychiatric Services*, *Journal of Substance Abuse Treatment*, *Journal of Studies on Alcohol and Drugs*, *Health Economics*, *Medical Care*, *Journal of Research in Crime and Delinquency*, *Health Services Research*, and *The American Journal of Psychiatry*.

Jesse Hinde, PhD, is a health economist with more than 10 years of experience conducting health policy research. He currently serves as the Associate Project Director for a cross-site evaluation of SAMHSA's Screening, Brief Intervention, and Referral to Treatment (SBIRT) program, a public health approach to reduce risky substance use implemented in medical settings. He is a recognized expert on the costs and financing of SBIRT services and the impacts of SBIRT on downstream health care costs. Other ongoing work includes CMS-funded analysis using the Arkansas all-payer claims database to assess the effects of a Medicaid-waivered

patient-centered medical home model on Medicaid and commercial health care utilization and costs. His past work includes federally-funded analyses conducted on randomized field experiments through the National Institute of Child Health and Human Development, the National Institute on Drug Abuse (NIDA), and the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and evaluations for SAMHSA's homeless program. He has also published analyses related to the costs and benefits of alcohol interventions, jail diversion programs, and workplace wellness programs.

- 1-5-3. Explain how you will ensure that your organization and external agents performing state-directed research will have access to the minimum necessary data to support specified research purposes and projects.

All electronic study data will be stored on a limited-access project shared drive on RTI's secure network servers; only study staff that have been authorized by the study director can access the shared drive. After study completion, all electronic files (e.g., notes, documents, reports) will be archived on RTI's project shared drive. Also, by March 31, 2019, RTI will have destroyed all data collected during the study. All RTI employees and contractors working on the project who have access to project data are required to sign a code of conduct that outlines how project staff should conduct research with human subjects which includes ensuring privacy and confidentiality.

- 1-5-4. List and briefly describe any unidentifiable or identifiable record-level data files you are planning to use in conjunction with the requested data. If the files will be linked explain the methodology for linking the data and how the identity of individuals and their PHI will be protected from disclosure.

We will not be linking VHCURES data to any other data.

- 1-5-5. Identify and briefly describe the funding source(s) for the proposed research including both internal and external sources that may be in the form of state and federal funding, grants, and other sources. Describe the relationship between the funding source(s) and your organization.

RTI International will fund the proposed research internally through an Independent Research and Development (IR&D) award.

- 1-5-6. Explain whether any component of the project was review and approved by an Institutional Review Board (IRB). If yes, attach the IRB review and approval under Attachment 7 to this application.

This study was reviewed by RTI's IRB and was determined to meet the requirements for category four exemption. This exemption applies to research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if these sources are publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Section 2: Data Management Plan

Section 2 relates to the policies and procedures your organization will use to ensure the proper management of the VHCURES limited use research data set and custom extracts derived from the data set. The GMCB recognizes the applicability of best practices for information security and privacy used in the CMS Data Privacy Safeguard Program (DPSP)¹ to the review of VHCURES DUA applications. Respond to every question about your organization's and those of approved entities external to your organization policies and procedures to ensure technical and administrative safeguards over the data.

Please answer the questions in each section with references to any attached documents including relevant page and/or section numbers. **Do not simply cite a cross-reference to the policy and procedure documents included under Attachment 2 and 6 of this application in lieu of answering each question. If questions are not answered completely, the application will be deemed incomplete.**

Any Project Review Forms (PRF) filed with this application for external agents under Attachment 4 may cite cross-references to this application for the same items in Section 2 below. Instructions are included on the PRFs.

¹ “Data Privacy Safeguard Program Information Security and Privacy Best Practices” listed under Additional Resources published on <https://www.resdac.org/resconnect/articles/158>

2-1. Physical Possession and Storage of Data Files

Include specific references to the Data Governance and Protection policies and procedures documents filed with this application under Attachments 2 and 6 in your responses to the items below. **Do not simply cite a cross-reference to the policy and procedure documents in lieu of answering each question.**

2-1-1. Describe how your organization will maintain an accurate and timely inventory of the VHCURES limited use research data set including original files received and any derived files used within your organization or released to external agents under state contracts and agreements.

The data will be kept in a manner that complies with all applicable laws and regulations. These objectives establish procedures for the systematic retention, storage, access, retrieval, and destruction of data:

- *Retain data in a secure and confidential manner for the minimum amount of time required by applicable law, regulation, or contract.*
- *Destroy data in a regular and methodical manner according to procedures and retention schedules.*

2-1-2. Describe how your organization will ensure and monitor the compliance of all members of research teams both in-house and those employed by approved external agents with privacy and security policies and procedures as described in the documentation filed under Attachments 2 and 6 to this application and as required by the DUA.

The researchers identified in 1-5-2 above are RTI employees, and no external agents will be in contact with the data. As a Hybrid Entity, RTI places immense importance on the effective operation of HIPAA privacy, Security, Breach Notification, and Enforcement Rules including the privacy and security provisions of the Health Information Technology for Economic and Clinical Health Act (HITECH Act) to protect Electronic Health Records (EHRs). RTI has designation of both HIPAA Security and Privacy Offices to review and ensure compliance with HIPAA regulations. These experienced professionals are experts in their field in implementing and monitoring robust policies, procedures, and IT environments which ensure the protection of PHI. Furthermore, each researcher on the RTI team has undergone rigorous HIPAA training through RTI’s online learning and development system.

2-1-3. Describe the procedures your organization will take to track the status and roles of the research team and notify GMCB of any project staffing changes.

The Principal Investigator, Susan Haber, will have the main responsibility of notifying GMCB of any project staffing changes. Specifically, we will notify GMCB when a staff member leaves the project and/or RTI and no longer has access to the data, and we will notify GMCB when a new staff member is brought on who requires access to the data. We will not permit any new staff members to access data until GMCB has been informed. In addition, the staff must have completed HIPAA training before accessing data files.

- 2-1-4. Describe your organization's training programs that are used to educate staff on how to protect sensitive data with personally identifiable information, protected health information, and other sensitive financial, socioeconomic, and personal information.

All RTI employees encountering PHI, including all the researchers listed in 1-5-2 above, must take a HIPAA training course presenting an overview of HIPAA, outlining its main components, and identifying who is covered by the Act. It examines the privacy provisions under HIPAA as they relate to protected health information (PHI). This course helps employees and business associates of covered entities recognize the key provisions of HIPAA, how their organizations are affected by HIPAA, and how the privacy rules impact them. This course was developed with subject matter support provided by the Labor & Employment Law Group of the law firm of Baker, Donelson, Bearman, Caldwell & Berkowitz, PC. Additionally, staff must complete refresher training on an annual basis to retain access to the HIPAA shares for projects involving PHI.

- 2-1-5. Describe the protocol that would be followed by your organization or that of approved external agents, if applicable, to report and mitigate a breach in the security of the data set. Who will be responsible for notifying the GMCB (and CMS as applicable to Medicare data available only to Vermont State Agencies and agents of the State) of any suspected incidents of a breach in the security of the VHCURES data?

In the event of a data security breach, the Principal Investigator, Susan Haber, would immediately notify the RTI Privacy Officer. It is the responsibility of the Privacy Officer to initiate GMCB notification processes if deemed appropriate. In this event, RTI would take all reasonable steps to mitigate the effects of such improper use or disclosure, cooperating with all reasonable requests by the GMCB towards that end. RTI would establish a process to notify individuals if their PHI had been breached. This would include individual notification, law enforcement notification (if applicable), and US Department of Health and Human Services (HHS) notification and breach notification documentation.

- 2-1-6. What actions will your organization and approved external entities take to physically secure the data files? This includes files in motion, or on servers, local workstations, and hard media.

Data Security Procedures

The only potential risk is loss of confidentiality. In order to protect participant confidentiality and any health-related information, RTI's evaluation team will adhere to the following protocol:

RTI will conduct the programming for all analyses on its computers and will employ its FISMA-compliant standard operating procedures and work in an enhanced security network when analyzing claims data with personal identifiers and personal health information.

All electronic communications must occur via a secure Internet connection. All transmissions will be encrypted with 128-bit encryption through secure socket layers (SSL) and verified by a VeriSign®, the leading SSL Certificate authority. Additionally, systems at RTI will implement username and password logins for all project staff, limited access to project applications and password-protected network drives, and confidentiality pledges for all staff.

Once the data are received at RTI, they will be handled with the same high-level security as other data in our possession. Data will be stored in a secure Microsoft SQL Server database utilizing a relational table structure, facilitating expedient data. The server, located at RTI, will be accessible only to the statisticians and analysts assigned to this project. Secure passwords are required before any data are sent in an encrypted form. Other individuals not associated with the project will not be able to access the data without permission from the Principal Investigator. Data will not be released to any individual or organization outside the research team.

Furthermore, RTI's computer network is protected by an Internet firewall. All traffic between the RTI network and the Internet passes through this single connection point, protecting all systems connected to the RTI network. The firewall is programmed with a set of rules to determine if network access is in compliance with RTI's network security policy before allowing access to the RTI network. For additional security, the firewall logs all incoming traffic from the Internet to the RTI network.

Upon completion of the study, all confidential materials will be securely destroyed according to RTI's "Closing out a Data Use Agreement" 5-step procedure. The Project Director (PD) will discern the requirements for termination of DUA/MTAs through direct contact with the provider organization. If no standard forms are required by the provider organization, the RTI data return/destruction certification template will be used. PD will determine the requirements for destruction from the provider organization. Moving forward, PD will work with Corporate Records and Compliance Services (CRCS) to have data and/or material destroyed. Once the data and/or materials are destroyed, the PD will certify that the data/material has been destroyed by completing the required form from the provider institute or RTI's Data Destruction/Return certification template. Finally, the PD will sign the certificate and send the original signed certification of data destruction to the appropriate contact person at the provider organization with copies directed to Corporate Records and Compliance Services.

- 2-1-7. Please explain if your organization intends to transmit, store, or transfer the data set or any derived files outside the continental United States.

N/A. RTI does not intend to transmit, store, or transfer the data set or any derived files outside the continental United States.

2-2. Data Sharing, Electronic Transmission, Distribution

Include specific references to the Data Governance and Protection policies and procedures documents filed with this application under Attachments 2 and 6 in your responses to the items below. **Do not simply cite a cross-reference to the policy documents in lieu of answering each question.**

- 2-2-1. Describe what your organization's policies and procedures will be for sharing, transmitting, and distributing the VHCURES data set and any derived files.

RTI will conduct the programming for all analyses on its computers and will employ its FISMA-compliant standard operating procedures and work in an enhanced security network when analyzing claims data with personal identifiers and personal health information.

All electronic communications must occur via a secure Internet connection. All transmissions will be encrypted with 128-bit encryption through secure socket layers (SSL) and verified by a VeriSign®, the leading SSL Certificate authority. Additionally, systems at RTI will implement username and password logins for all project staff, limited access to project applications and password-protected network drives, and confidentiality pledges for all staff.

RTI Policy 12.5.4 broadly covers the sharing, transmitting, and distributing of Sensitive Information, including Personal Identifiable Information (PII) and HIPAA and other protected health information.

Policy 12.5.4 governs the transmission of Sensitive Information. RTI policies and procedures and the laws of the U.S. and foreign governments impose specific requirements upon the disclosure of Sensitive Information. Failure to comply with these requirements is a violation of policies and procedures and may lead to a violation of law. Accordingly, before transmitting Sensitive Information, the sender must verify that:

- The information is of a type that may be appropriately transmitted.
- Any required legends, labels, or other markings have been applied. If the information falls into more than one Sensitive Information category, all applicable legends, labels, or other markings must be applied.
- The intended recipient is authorized to receive the Sensitive Information.
- The selected Transmittal method is secure and complies with this policy and the laws of the recipient country.

ITS Policy and Procedure 14.2 Information Security and Classification of Electronic Information, provides additional requirements for transmitting Sensitive Information in electronic form.

- 2-2-2. The GMCB's preferred method of transmission of the data files is through a secure File Transfer Protocol (SFTP) transmission. If you anticipate requesting encrypted hard media, please explain the reasons that SFTP is not an option.

N/A. SFTP transmission will suffice.

- 2-2-3. Would your organization and approved external agents be interested in accessing a hosted data enclave or a researchers' workbench environment eliminating the transmission of data files via SFTP or via encrypted hard media outside of the hosted enclave? If yes, would the interest hold if there are fees for this service? If not interested at all or cautious, please explain your concerns.

We would not be interested in accessing a hosted data enclave or a researchers' workbench environment due to the extra fees applied for these services. Furthermore, the SFTP method has worked well for data transfers in the past and RTI has the policies, procedures, and infrastructure to support it.

- 2-2-4. Describe your organization's methods and those of approved external agents for tracking, monitoring, and auditing access and use of sensitive data such as the VHCURES data set.

RTI Policy 12.5.1 broadly covers the monitoring of access and use of sensitive of Sensitive Information, including Personal Identifiable Information (PII) and HIPAA and other protected health information. It ensures that working relationships, physical and electronic safeguards, contract provisions, federal regulations and RTI policies all work together to ensure that access to sensitive information is appropriately restricted. Compliance with access requirements ultimately rests with each individual employee to ensure that they take every precaution to safeguard the information entrusted into their care.

Access is usually determined by the type of information and the need for the access. No external agents who will have access to this data.

RTI's HIPAA environment meets all administrative, physical, and technical security standards. Policies and procedures, including minimum necessary access requirements, active log monitoring, and training, are documented. RTI's technical controls include but are not limited to regular vulnerability scanning, automated audit log monitoring, intrusion detection and prevention measures, and periodic control auditing to ensure compliance with applicable regulations. Verification of RTI staff access to client HIPAA data is performed quarterly to ensure appropriateness of access according to policy. Further, RTI establishes and implements plans for emergency response, backup operations, and disaster recovery of information systems.

- 2-2-5. Describe the policies and procedures and procedures your organization and approved external agents use to define data access privileges for individual users of the data, including the Principal Investigator, Data Custodian, analysts and researchers, administrative support, and IT support.

Policy 12.5.2, Disclosure of Information, states that disclosure of Sensitive Information should be restricted to individuals on a need to know basis. Employees are prohibited from using any information obtained or disclosed in the course of their employment for personal gain or business venture or in any manner inconsistent with applicable restrictions pertaining to the type of sensitive information.

Data is stored on project-specific HIPAA-compliant secure share drives. Only authorized staff can access the share drive folders; access is denied to non-project staff.

Explain the use of technical safeguards for data access (which may include password protocols, log-on/log-off protocols, session time out protocols, and encryption for data in motion and data at rest).

RTI will conduct the programming for all analyses on its computers and will employ its FISMA-compliant standard operating procedures and work in an enhanced security network when analyzing claims data with personal identifiers and personal health information.

RTI passwords are a minimum of 9 characters, meet complexity requirements, and have a maximum age of 60 days. Following 900 seconds of inaction, RTI computers default to a password-protected screen saver. (RTI_ITS_SOP_0540)

All electronic communications must occur via a secure Internet connection. All transmissions will be encrypted with 128-bit encryption through secure socket layers (SSL) and verified by a VeriSign®, the leading SSL Certificate authority. Additionally, systems at RTI will implement username and password logins for all project staff, limited access to project applications and password-protected network drives, and confidentiality pledges for all staff.

Once the data are received at RTI, they will be handled with the same high-level security as other data in our possession. Data will be stored in a secure Microsoft SQL Server database utilizing a relational table structure, facilitating expedient data. The server, located at RTI, will be accessible only to the statisticians and analysts assigned to this project. Secure passwords are required before any data are sent in an encrypted form. Other individuals not associated with the project will not be able to access the data without permission from the Principal Investigator. Data will not be released to any individual or organization outside the research team.

Furthermore, RTI's computer network is protected by an Internet firewall. All traffic between the RTI network and the Internet passes through this single connection point, protecting all systems connected to the RTI network. The firewall is programmed with a set of rules to determine if network access is in compliance with RTI's network security policy before allowing access to the RTI network. For additional security, the firewall logs all incoming traffic from the Internet to the RTI network.

- 2-2-6. If approved external agents will have access to the data please describe how that organization's analysts will access the data file, e.g., VPN connection, travel to your organization, or house the data at other locations.

N/A. No external agents will have access to this data.

- 2-2-7. If additional copies of the data will be housed in separate locations, list the locations and describe how the data will be transferred to these locations.

N/A. No additional copies of data will be housed in separate locations.

2-3. Data Reporting and Publication

- 2-3-1. Explain your process for reviewing publications prior to dissemination to ensure accurate and appropriate representation of your data sources, analytic methodology, results, caveats, and disclaimers. Describe how your publications will be reviewed to ensure compliance with requirements in the DUA addressing small n suppression, disclaimer of any GMCB endorsement of findings, and data source citation.

RTI reports undergo review by project staff. DUA requirements are re-reviewed and publications will be reviewed by a senior statistician, a senior subject matter expert, and an experienced editor to ensure that they comply with all DUA requirements, including suppression of cells with small ns. Any publications will include a disclaimer of GMCB endorsement of findings and will cite VHCURES as the data source.

2-4. Completion of Research Tasks and Data Destruction

- 2-4-1. Describe how you will complete the Certificate of Data Destruction for the data set and derived files stored by your organization or by approved external agents and how the data will be deleted, destroyed or rendered unreadable by all parties with access to the files upon completion of the project.

Upon completion of the study, all confidential materials will be securely destroyed according to RTI's "Closing out a Data Use Agreement" 5-step procedure. The Project Director/Manager (PD/PM) will discern the requirements for termination of DUA/MTAs through direct contact with the provider organization (i.e., GMCB). If no standard forms are required by the provider organization, the RTI data return/destruction certification template will be used. PD/PM will determine the requirements for destruction from the provider organization. Moving forward, PD/PM will work with Corporate Records and Compliance Services (CRCS) to have data and/or material destroyed. Once the data and/or materials are destroyed, the PD/PM will certify that the data/material has been destroyed by completing the required form from the provider institute or RTI's Data Destruction/Return certification template.

RTI Records Management Policy 1.9 and information technology services (ITS) policy 1011 cover the destruction of Sensitive Information. The RTI Records Management Policy states that records containing sensitive information must be destroyed in a manner that completely obliterates their contents and renders the records unreadable and unusable. Sensitive records must be destroyed in a timely manner and kept in a secure location until destruction occurs. Appropriate measures must be taken to ensure the security and confidentiality of recorded information during all phases of the destruction process, including pickup and transport of records from RTI's locations to the destruction site. It is the group or unit's responsibility to ensure that confidential records are destroyed in full conformity with this guideline.

The RTI ITS Media Protection policy states that it is the responsibility of ITS Operations Staff to ensure that all fixed electronic media is fully sanitized prior to reuse or disposal to preclude access to any sensitive information that may have been written to the media. ITS Staff must maintain record of all hardware wipes and disposals and are responsible for complying with all ITS Technical Operating Procedures and ITS standards that are defined and referenced. This responsibility includes using the approved tools (e.g. DBAN) to complete all tasks necessary for wiping, disposing and controlling all fixed electronic media.

After the data has been destroyed, the PD/PM will sign the certificate and send the original signed certification of data destruction to the appropriate contact person at the provider organization with copies directed to Corporate Records and Compliance Services.

- 2-4-2. Describe your organization's policies and procedures and those of external agents used to protect VHCURES data files when individual staff members of research teams terminate their participation in research projects (which may include staff exit interviews, return of passkeys, and immediate access termination for example).

The following items are part of the RTI International separation of employment process:

- *Exit interview with HR Business Partner*
- *Transfer (or close if appropriate) projects involving human subjects for which you are a project leader and notify the RTI Institutional Review Board (IRB)*
- *If you have a Security Clearance, contact, Industrial Security to arrange for a security debriefing*
- *Return ID badge, parking pass, access cards, computer, laptop, cell phone (remove pass code), Ipad/tablet (remove passcode), DIGIPASS token, thumb drives, CDs, DVDs, portable drives, any storage devices containing RTI-related/client-related business/research information*

2-4-3. Describe your organization's policies and procedures to ensure original or derived data files, including non-published aggregate reports, are not used following the completion of the project.

According to RTI Policy 14.1.1, Rules of Behavior, third Party Proprietary Information must be destroyed or returned to the owner in accordance with the data use agreement (DUA) under which the information was received. If the information is to be destroyed, RTI will follow the specific destruction instructions outlined in the DUA.

Section 3: Project Team

In Section 3-5, list the anticipated individual users within your organization and external agents such as contractors and subcontractors, and project roles. **Signed IUAs for individual users within your organization and those employed by external entities accessing the data must be filed prior to receipt of the VHCURES data set.**

3-1. Authorized User (Can legally bind the applicant's organization to agreements)

Please provide contact information for the Authorized User's signatory.

Name and Title of Signatory for the Authorized User

Tony Dawson, Supply Chain Specialist

Organization Name

RTI International

Street Address

3040 E Cornwallis Rd

City

Research Triangle Park

State

NC

Zip

27709

Telephone

919-485-5526

Email

tdawson@rti.org

3-2. Principal Investigator

Please provide contact information for the PI if different person than the AU.

☐ Same as Authorized User Signatory

Name and Title of Principal Investigator

Susan Haber, Director, Program on Health Coverage for Low-Income and Uninsured Populations

Organization Name

RTI International

Street Address

307 Waverley Oaks Rd., Suite 101

City

Waltham

State

MA

Zip

02452

Telephone

781-434-1721

Email

shaber@rti.org

3-3. Data Custodian(s)

Provide contact information for the data custodian for your organization and the data custodians for any external agents such as state contractors, subcontractors or other organizations that will storing the VHCURES data set or derived files.

Name and Title of Data Custodian (State Agency)		
Organization		
Street Address		
City	State	Zip
Telephone		Email

Name and Title of Data Custodian		
<i>Jennifer Popovic</i>		
Organization		
<i>RTI International</i>		
Street Address		
<i>307 Waverley Oaks Rd., Suite 101</i>		
City	State	Zip
<i>Waltham</i>	<i>MA</i>	<i>02452</i>
Telephone		Email
<i>781-434-1767</i>		<i>jpopovic@rti.org</i>

Name and Title of Data Custodian		
Organization		
Street Address		
City	State	Zip
Telephone		Email

3-4. Individual Users

Identify all individuals within your organization and external agents who will be participating on this project. These individuals may be project managers, analysts, IT professionals, or any other person who may have access to row-level data or aggregate reports prior to the suppression of small n. You must attach a signed individual user affidavit for each of these individual users prior to the receipt of the data after the DUA is approved including any users not identified on this list when this application was submitted.

Name	Organization	Project Role or Title
Susan Haber	RTI International	Principal investigator
Jennifer Popovic	RTI International	Data custodian/Senior programmer
Tami Mark	RTI International	Senior advisor
Alex Cowell	RTI International	Senior economist
Jesse Hinde	RTI International	Economist
Elise Hooper	RTI International	Programmer
Elliott Liebling	RTI International	Junior research analyst

Section 4: Data Procurement and Price

The authorized user will receive the data from the GMCB's designated data processing vendor for a fee determined by the number of years of data and whether any complex customization is required. The authorized use may contact the vendor in advance to confirm the exact pricing that generally runs about \$5,200 for an extract of paid claims data spanning five (5) years. Prices are subject to change.

In the future, the GMCB may be offering access to the data through a hosted data enclave. This would eliminate or be an additional option for accessing the data via electronic SFTP transmission of the record-level data. GMCB will notify the authorized user for the DUA when this service becomes available as an option and how it will work as to number of user seats and pricing.

There may be fees for custom extracts. Typically, custom extracts are generated to support the data stewardship principle of disclosing the minimum necessary data to support the research purpose. Data users may be authorized to access a secured data enclave hosted by the vendor. Use of services provided by the GMCB's data consolidation vendor may require payment of a fee to the vendor. Fees will be determined on a case-by-case basis. Onpoint Health Data will manage any invoicing for fees.

The GMCB's designated vendor for the VHCURES Limited Use Research Data Set is:

Onpoint Health Data

Mailing Address:

75 Washington Avenue, Suite 1E
Portland, ME 04101

Physical Address:

55 Washington Avenue
Portland, ME 04101

Main Phone: (207) 623-2555

www.onpointhealthdata.org

Section 5: Data Transmission and Receipt

Use of an electronic secure File Transfer Protocol (SFTP) is the preferred mode of release for approved data extracts. Onpoint Health Data, the GMCB’s data consolidation and warehousing vendor will provide an “Electronic Data Transmission Readiness and Logistics Checklist” to assist you in determining whether you are able to receive the transmission.

Please identify your primary contact below for setting up the logistics for SFTP transmission of the approved data extract. The primary contact must either be the Authorized User or Principal Investigator or Data Custodian identified on the DUA or be designated by the AU or PI.

As noted under Section 4, the GMCB may offer access to the data via a hosted data enclave in the future. Authorized users will be notified when this service becomes available.

Primary Contact for Planning Data Transmission Logistics

Name: <i>Jennifer Popovic</i>
Title/Role in the Project: <i>Data custodian/Senior programmer</i>
If not AU, PI or DC, designated by:
Email Address: <i>jpopovic@rti.org</i>
Phone Number: <i>781-434-1767</i>
Organization/Agency Affiliation: <i>RTI International</i>
Street, City, ZIP Address: <i>307 Waverley Oaks Rd., Suite 101, Waltham, MA 02452</i>

Section 6: Signatures

All statements made in this application are true, complete, and correct to the best of my knowledge.

Authorized User Name: Tony Dawson

Signature:



Date:

4/26/2018

Principle Investigator Name (if different from Authorized User): Susan Haber

Signature:

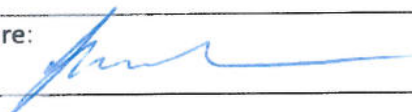


Date:

4/23/18

Data Custodian Name: Jennifer Popovic

Signature:



Date:

4/23/18

GMCB Processing Section

For GMCB Use Only

Applicant Organization or Entity Name:

Data Types: Commercial ()

Medicaid ()

Medicare ()

Application Receipt Date/GMCB Initials:

Date Application Deemed Complete:

DVHA Application Approval Date:

GMCB Application Approval Date/GMCB Initials:

Date Applicant Notified of Approval:

Application Disapproval Date:

Date Applicant Notified of Disapproval/GMCB Initials

Summary of reasons for disapproval:

Date Application Deemed Incomplete/GMCB Initials:

Date Applicant Notified Application Deemed Incomplete:

Summary of reasons the application deemed incomplete:

Date Application Deemed Incomplete Resubmitted:

DVHA Application Approval Date:

GMCB Resubmitted Application Approval Date /GMCB Initials:

Date Applicant Notified of Approval of Resubmitted Application:

Resubmitted Application Disapproval Date/GMCB initials:

Summary of reasons for disapproval:

Data Security Procedures

The only potential risk is loss of confidentiality. In order to protect participant confidentiality and any health related information, RTI's evaluation team will adhere to the following protocol:

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person at the provider organization with copies directed to Corporate Records and Compliance Services.

ID	Common Name	Description	Origin	Release Status ^{1,2}	Request Status	If YES to Request Status, explain how the requested field supports the research purpose
EL-CORE001	Eligibility Record ID	This field contains an ID that identifies a unique eligibility record.	This is a value-added field created by Onpoint.	Unrestricted	X	
EL-CORE003	Submitter ID	This field contains an ID that uniquely identifies a submitter.	This is a value-added field created by Onpoint.	Restricted	() YES (X) NO	
EL-CORE005	Coverage Class	This field identifies the type of coverage for the member during the reported period.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
EL-CORE007	Internal Member ID	This field contains an ID that represents a unique member.	This is a value-added field created by Onpoint.	Unrestricted	X	
EL-CORE009	Member's Relationship Code	This field contains a code that indicates the member's relationship to the subscriber or the insured.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
EL-CORE011	Insurance Type / Product Code	This field contains a code that identifies the member's type of insurance or insurance product.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
EL-CORE013	Primary Insurance Indicator Code	This field contains a code that indicates if the member has primary coverage or instead has secondary/tertiary coverage.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
EL-CORE014	Member Gender Code	This field contains a code that indicates the member's gender.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
EL-CORE015	Member Age (90+ Aggregate)	This field identifies the member's age in years.	This is a value-added field created by Onpoint.	Unrestricted	X	
EL-CORE016	Age 65+ Flag	This field identifies whether the member was 65 years of age or older.	This is a value-added field created by Onpoint.	Unrestricted	X	
EL-CORE017	Out-of-State Flag	This field identifies whether the member was domiciled within the state of Vermont.	This is a value-added field created by Onpoint.	Unrestricted	X	
EL-CORE018	Member Coverage Start Date	This field identifies the first date of the member's insurance coverage within this reporting period.	This is a value-added field created by Onpoint.	Unrestricted	X	
EL-CORE019	Member Coverage End Date	This field identifies the last date of the member's insurance coverage.	This is a value-added field created by Onpoint.	Unrestricted	X	
EL-CORE020	Full Medicaid Coverage Flag	This field contains a code that identifies whether or not a member had full Medicaid coverage for the reported membership month.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
EL-CORE022	Aid Category Code	This field contains a code that identifies the member's Medicaid aid category based on eligibility date.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
EL-CORE024	Federal Poverty Level Code	This field contains a code that identifies the member's Medicaid federal poverty level based on eligibility date.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
EL-CORE026	Long-Term Care (LTC) Coverage Code	This field contains a code that identifies the member's Medicaid long-term coverage based on eligibility date.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
EL-CORE028	Dual-Eligibility Code	This field contains a code that identifies the member's dual coverage based on eligibility date.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	

EL-CORE030	Chronic Care Code	This field contains a code that identifies the member's chronic care designation based on eligibility date.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
EL-CORE032	Coverage Level Code	This field contains a code that identifies the member's coverage level based on eligibility date.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
EL-CORE034	Coverage Type Code	This field contains a code that identifies the member's coverage type based on eligibility date.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
EL-CORE037	Eligibility Code	This Medicaid-supplied field identifies whether or not the member was an eligible beneficiary as of the 15th of the month.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
EL-SUP001	Eligibility Record ID	This field contains an ID that identifies a unique eligibility record.	This is a value-added field created by Onpoint.	Unrestricted	X	
EL-SUP006	PCMH Initiative Code	This field contains the PCMH initiative code for the reported member.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
EL-SUP016	Market Category Code	This field contains a code that indicates the type of policy sold by the insurer.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
EL-SUP018	Blueprint Service Area Code	This field contains a code that identifies a specific Blueprint Service Area.	This field is supplied as reported by Vermont Medicaid using the Blueprint Service Area element in the member eligibility file.	Unrestricted	X	
MEM-CORE001	Member ID	This field contains an ID that identifies a unique combination of a member's reported information.	This is a value-added field created by Onpoint.	Restricted	(X)YES ()NO	This field links to the Member ID Number element (MEMBERIDN) in the claims and membership data. We will need this variable to merge data files and create outcomes for our eligible population.
MEM-CORE003	Internal Member ID	This field contains an ID that represents a unique member.	This is a value-added field created by Onpoint.	Restricted	(X)YES ()NO	This field can be used to aggregate all records associated with a member. We will need this variable to merge data files and create outcomes for our eligible population.
MEM-CORE007	Member City	This field identifies the member's city of residence.	This field is supplied as reported to Onpoint by the submitter.	Restricted	()YES (X)NO	
MEM-CORE008	Member State or Province	This field identifies the member's state or province of residence using the two-character abbreviation defined by the U.S. Postal Service (for U.S. states) and Canada Post (for Canadian provinces).	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MEM-CORE009	Member ZIP/Postal Code	This field identifies the ZIP/postal code associated with the member's residence.	This field is supplied as reported to Onpoint by the submitter.	Restricted	(X)YES ()NO	We will need this variable to identify urban/rural location.
MEM-CORE014	Gender Code	This field contains a code that identifies the member's gender.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MEM-CORE016	Member Flag	This field flags whether this record is for a member (as opposed to for a subscriber).	This is a value-added field created by Onpoint.	Unrestricted	X	
MEM-CORE020	Subscriber Member ID	This field contains an ID that identifies a unique combination of a subscriber's reported information.	This is a value-added field created by Onpoint.	Restricted	()YES (X)NO	
MEM-CORE021	Subscriber Internal Member ID	This field contains an ID that represents a unique subscriber.	This is a value-added field created by Onpoint.	Restricted	()YES (X)NO	

MC-CORE001	Medical Claim Service-Line Record ID	This field contains an ID that identifies a unique service line of a submitted claim record.	This is a value-added field created by Onpoint.	Unrestricted	X	
MC-CORE003	Submitter ID	This field contains an ID that uniquely identifies a submitter.	This is a value-added field created by Onpoint.	Restricted	() YES (X) NO	
MC-CORE005	Insurance Type / Product Code	This field contains a code that identifies the member's type of insurance or insurance product.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-CORE007	Line Counter	This field contains the line number for this service.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-CORE008	Member ID	This field contains an ID that identifies a unique combination of a member's reported information.	This is a value-added field created by Onpoint.	Restricted	(X) YES () NO	This field links to the Member ID Number element (MEMBERIDN) in the claims and membership data, which we will need to create outcomes for our eligible population.
MC-CORE009	Internal Member ID	This field contains an ID that represents a unique member.	This is a value-added field created by Onpoint.	Restricted	(X) YES () NO	This field can be used to aggregate all records associated with a member. We will need this variable to merge data files and create outcomes for our eligible population.
MC-CORE011	Member's Relationship Code	This field contains a code that indicates the member's relationship to the subscriber or the insured.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-CORE012	Member Gender Code	This field contains a code that indicates the member's gender.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-CORE013	Member Age (90+ Aggregate)	This field identifies the member's age in years.	This is a value-added field created by Onpoint.	Unrestricted	X	
MC-CORE014	Age 65+ Flag	This field identifies whether the member was 65 years of age or older.	This is a value-added field created by Onpoint.	Unrestricted	X	
MC-CORE015	Out-of-State Flag	This field identifies whether the member was domiciled within the state of Vermont.	This is a value-added field created by Onpoint.	Unrestricted	X	
MC-CORE016	First Paid Date	This field identifies the first payment date for the rendered service.	This is a value-added field created by Onpoint.	Unrestricted	X	
MC-CORE017	Last Paid Date	This field identifies the last payment date for the rendered service.	This is a value-added field created by Onpoint.	Unrestricted	X	
MC-CORE018	Date of Service (From)	This field identifies the first date of service for this service line.	This field is supplied as reported to Onpoint by the submitter.	Restricted	(X) YES () NO	We will need these variables to assign services to an episode of OUD treatment.
MC-CORE019	Date of Service (Through)	This field identifies the last date of service for this service line.	This field is supplied as reported to Onpoint by the submitter.	Restricted	(X) YES () NO	We will need these variables to assign services to an episode of OUD treatment.
MC-CORE020	Admission Date	This field provides the date of the inpatient admission.	This field is supplied as reported to Onpoint by the submitter.	Restricted	(X) YES () NO	We will need these variables to assign services to an episode of OUD treatment.
MC-CORE021	Discharge Date	This field identifies the discharge date of the patient from inpatient care.	This field is supplied as reported to Onpoint by the submitter.	Restricted	(X) YES () NO	We will need these variables to assign services to an episode of OUD treatment.
MC-CORE023	Place of Service Code	This field contains a code that indicates the type of site where the service was performed.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-CORE025	Type of Bill Code	This field contains a code that identifies the reported type of bill.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-CORE026	Claim Type ID	This field identifies an ID for the type of claim (e.g., facility, professional, etc.) used to report this service line.	This is a value-added field created by Onpoint.	Unrestricted	X	

MC-CORE027	Type of Setting ID	This field provides additional granularity regarding the type of claim (e.g., inpatient, outpatient, provider, lab, etc.).	This is a value-added field created by Onpoint.	Unrestricted	X	
MC-CORE028	Place of Setting ID	This field identifies the setting in which the care was rendered (e.g., hospital, swing bed, skilled nursing facility, etc.).	This is a value-added field created by Onpoint.	Unrestricted	X	
MC-CORE030	Quantity	This field contains a count of performed services.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-CORE031	Charge Amount	This field identifies the total charges for the service.	This field is supplied as reported to Onpoint by the submitter.	Restricted	() YES (X) NO	
MC-CORE032	Paid Amount	This field identifies the total dollar amount paid to the provider, including all health plan payments and excluding all member payments and withholdings from providers.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-CORE033	Copay Amount	This field identifies the preset, fixed dollar amount payable by a member, often on a per visit/service basis. For the MN APCD, this file is used to combine and report both the copay and the coinsurance amounts.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-CORE034	Coinsurance Amount	This field identifies the dollar amount that a member must pay toward the cost of a covered service, which is often a percentage of total cost.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-CORE035	Deductible Amount	This field identifies the dollar amount that a member must pay before the health plan benefits will begin to reimburse for services.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-CORE041	Claim Status Code	This field contains a code that identifies the status of the claim line — whether paid as primary, paid as secondary, denied, etc.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-CORE043	Procedure Code	This field contains the reported procedure code for the service rendered.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-CORE045	Procedure Modifier Code (1)	This field identifies a CPT procedure modifier, which is used to indicate that a service or procedure has been altered by some specific circumstance but has not changed in its definition or code.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-CORE047	Procedure Modifier Code (2)	This field identifies a CPT procedure modifier, which is used to indicate that a service or procedure has been altered by some specific circumstance but has not changed in its definition or code.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-CORE053	Revenue Code	This field contains a code that identifies the revenue category for the rendered service.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-CORE054	ICD Version Indicator	This field contains a code that identifies the version of ICD used to report this service line.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	

MC-CORE056	Diagnosis Code	This field contains a code that identifies a distinct diagnosis.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-CORE058	ICD Procedure Code	This field contains the principal ICD procedure code for the service rendered.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-CORE060	Aid Category Code	This field contains a code that identifies the member's Medicaid aid category based on service date.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-CORE062	Discharge Status Code	This field contains a code that indicates the status for the patient discharged from an inpatient stay.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-CORE063	Orphaned Adjustment Flag	This field contains a flag that identifies a reported adjustment record for which the original claim was not submitted.	This is a value-added field created by Onpoint.	Unrestricted	X	
MC-CORE064	Denied Claim Flag	This field contains a flag that identifies a claim that was denied.	This is a value-added field created by Onpoint.	Unrestricted	X	
MC-CORE065	Emergency Room Flag	This field contains a code that is used to identify specific emergency room (ER) revenue or procedure codes within a claim.	This is a value-added field created by Onpoint.	Unrestricted	X	
MC-SUP001	Medical Claim Service-Line Record ID	This field contains an ID that identifies a unique service line of a submitted claim record.	This is a value-added field created by Onpoint.	Unrestricted	X	
MC-SUP008	Admission Point of Origin Code	This field contains a code that indicates the source of admission.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-SUP010	Admission Type Code	This field identifies the type of admission code for the inpatient hospital claim.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-SUP012	National Drug Code	This field contains the National Drug Code (NDC) reported for this service line.	This field is supplied as reported to Onpoint by the submitter using collection field (National Drug Code).	Unrestricted	X	
MC-SUP013	APC	This field identifies the Ambulatory Payment Classification (APC) when reported.	This field is supplied as reported to Onpoint by the submitter using collection field (APC).	Unrestricted	X	
MC-SUP014	APC Version	This field identifies the version of the Ambulatory Payment Classification (APC) reported in the APC field (apc; MC073).	This field is supplied as reported to Onpoint by the submitter using collection field (APC Version).	Unrestricted	X	
MC-SUP015	DRG	This field identifies the Diagnosis Related Group (DRG).	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-SUP016	DRG Version	This field identifies the version of the Diagnosis Related Group (DRG) reported in the DRG field.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-SUP032	Category of Service Code	This field contains a code that identifies the member's Medicaid category of service.	This field is supplied as reported to Onpoint by Medicaid.	Unrestricted	X	
MC-SUP034	Fund Source Code	This field contains a code that identifies a specific funding source.	This field is supplied as reported to Onpoint by Medicaid.	Unrestricted	X	
MC-DIAG001	Medical Claim Service-Line Record ID	This field contains an ID that identifies a unique service line of a submitted claim record.	This is a value-added field created by Onpoint.	Unrestricted	X	
MC-DIAG002	Diagnosis Code - Reported Order	This field identifies the order in which the diagnosis code was reported within the context of its specific diagnosis category.	This is a value-added field created by Onpoint.	Unrestricted	X	

MC-DIAG003	Diagnosis Type ID	This field identifies the type of reported Diagnosis Code (diagnosis_code) (e.g., admitting, principal, other, etc.).	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-DIAG005	ICD Version Indicator	This field contains a code that identifies the version of ICD used to report this service line.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-DIAG007	Diagnosis Code	This field contains a code that identifies a distinct diagnosis.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-PROC001	Medical Claim Service-Line Record ID	This field contains an ID that identifies a unique service line of a submitted claim record.	This is a value-added field created by Onpoint.	Unrestricted	X	
MC-PROC002	ICD Procedure Code - Reported Order	This field identifies the order in which the ICD procedure code was reported within the context of its specific code category.	This is a value-added field created by Onpoint.	Unrestricted	X	
MC-PROC004	ICD Version Indicator	This field contains a code that identifies the version of ICD used to report this service line.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-PROC006	ICD Procedure Code	This field contains the principal ICD procedure code for the service rendered.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MC-PRV001	Medical Claim Service-Line Record ID	This field contains an ID that identifies a unique service line of a submitted claim record.	This is a value-added field created by Onpoint.	Unrestricted	X	
MC-PRV003	Rendering Provider ID	This field contains an ID that identifies a unique combination of a rendering provider's reported information.	This is a value-added field created by Onpoint.	Unavailable for abortions	X	
MC-PRV004	Rendering Provider Internal Provider ID	This field contains an ID that represents a unique provider.	This is a value-added field created by Onpoint.	Unavailable for abortions	X	
MC-PRV005	Billing Provider ID	This field contains an ID that identifies a unique combination of a billing provider's reported information.	This is a value-added field created by Onpoint.	Unavailable for abortions	X	
MC-PRV006	Billing Provider Internal Provider ID	This field contains an ID that represents a unique provider.	This is a value-added field created by Onpoint.	Unavailable for abortions	X	
MC-PRV007	Attending Provider ID	This field contains an ID that identifies a unique combination of an attending provider's reported information.	This is a value-added field created by Onpoint.	Unavailable for abortions	X	
MC-PRV008	Attending Provider Internal Provider ID	This field contains an ID that represents a unique provider.	This is a value-added field created by Onpoint.	Unavailable for abortions	X	
PC-CORE001	Pharmacy Claim Record ID	This field contains an ID that identifies a unique pharmacy claim record.	This is a value-added field created by Onpoint.	Unrestricted	X	
PC-CORE003	Submitter ID	This field contains an ID that uniquely identifies a submitter.	This is a value-added field created by Onpoint.	Restricted	(X) YES (X) NO	
PC-CORE004	Submitter Claim Control Number (Er	This field contains an encrypted version of the claim number used by the data submitter to internally track the claim.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE005	Line Counter	This field contains the line number for this service.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE006	Member ID	This field contains an ID that identifies a unique combination of a member's reported information.	This is a value-added field created by Onpoint.	Restricted	(X) YES (X) NO	This field links to the Member ID Number element (MEMBERIDN) in the claims and membership data, which we will need to create outcomes for our eligible population.

PC-CORE007	Internal Member ID	This field contains an ID that represents a unique member.	This is a value-added field created by Onpoint.	Restricted	(X)YES ()NO	This field can be used to aggregate all records associated with a member. We will need this variable to merge data files and create outcomes for our eligible population.
PC-CORE009	Insurance Type / Product Code	This field contains a code that identifies the member's type of insurance or insurance product.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE010	Member Gender Code	This field contains a code that indicates the member's gender.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE011	Member Age (90+ Aggregate)	This field identifies the member's age in years.	This is a value-added field created by Onpoint.	Unrestricted	X	
PC-CORE012	Age 65+ Flag	This field identifies whether the member was 65 years of age or older.	This is a value-added field created by Onpoint.	Unrestricted	X	
PC-CORE013	Out-of-State Flag	This field identifies whether the member was domiciled within the state of Vermont.	This is a value-added field created by Onpoint.	Unrestricted	X	
PC-CORE015	Member's Relationship Code	This field contains a code that indicates the member's relationship to the subscriber or the insured.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE017	Aid Category Code	This field contains a code that identifies the member's Medicaid aid category based on eligibility date.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE018	Date Prescription Filled	This field identifies the date on which the prescription was filled.	This field is supplied as reported to Onpoint by the submitter.	Restricted	(X)YES ()NO	We will need these variables to assign services to an episode of OUD treatment.
PC-CORE019	First Paid Date	This field contains the first paid date associated with the claim.	This is a value-added field created by Onpoint.	Unrestricted	X	
PC-CORE020	Last Paid Date	This field contains the last paid date associated with the claim.	This is a value-added field created by Onpoint.	Unrestricted	X	
PC-CORE021	National Drug Code	This field contains the National Drug Code (NDC) reported for this claim.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE022	Drug Name	This field contains the text name of the dispensed drug.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE023	New Prescription or Refill	This field contains a code that identifies whether this was a new prescription or a refill.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE024	Quantity Dispensed	This field identifies the total unit dosage in metric units.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE025	Days' Supply	This field identifies the days' supply for the prescription based on the metric quantity dispensed.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE026	Thirty-Day Equivalency	This field reports the number of thirty-day equivalencies associated with this prescription.	This is a value-added field created by Onpoint.	Unrestricted	X	
PC-CORE027	Charge Amount	This field identifies the total charges for the service.	This field is supplied as reported to Onpoint by the submitter.	Restricted	()YES (X)NO	
PC-CORE028	Paid Amount	This field identifies the total dollar amount paid to the provider, including all health plan payments and excluding all member payments and withholdings from providers.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	

PC-CORE029	Copay Amount	This field identifies the preset, fixed dollar amount payable by a member, often on a per visit/service basis.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE030	Coinsurance Amount	This field identifies the dollar amount that a member must pay toward the cost of a covered service, which is often a percentage of total cost.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE031	Deductible Amount	This field identifies the dollar amount that a member must pay before the health plan benefits will begin to reimburse for services.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE032	Dispensing Fee	This field reports the amount charged for dispensing the prescription.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE033	Ingredient Cost / List Price	This field reports the cost of the drug that was dispensed.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE034	Postage Amount Claimed	This field reports the cost of postage included in the Paid Amount field.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE036	Claim Status Code	This field contains a code that identifies the status of the claim — whether paid as primary, paid as secondary, denied, etc.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE037	Denied Claim Flag	This field contains a flag that identifies a claim that was denied.	This is a value-added field created by Onpoint.	Unrestricted	X	
PC-CORE039	Generic Drug Indicator Code	This field contains a code that identifies whether the dispensed drug was a branded drug or a generic drug.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE041	Compound Drug Indicator Code	This field contains a code that indicates whether or not the dispensed drug was a compound drug.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE043	Dispense as Written Code	This field contains a code that identifies the instructions given to the pharmacist for filling the prescription.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PC-CORE044	Orphaned Adjustment Flag	This field contains a flag that identifies a reported adjustment record for which the original claim was not submitted.	This is a value-added field created by Onpoint.	Unrestricted	X	
PC-CORE045	Medicare Part D Duplicate Flag	This field designates if this is a duplicate Part D record reported by both Medicare and a commercial part D plan.	This is a value-added field created by Onpoint.	Unrestricted	X	
PC-PRV001	Pharmacy Claim Record ID	This field contains an ID that identifies a unique pharmacy claim record.	This is a value-added field created by Onpoint.	Unrestricted	X	
PC-PRV003	Pharmacy Provider ID	This field contains an ID that identifies a unique combination of a pharmacy's reported information.	This is a value-added field created by Onpoint.	Unrestricted	X	
PC-PRV004	Pharmacy Internal Provider ID	This field contains an ID that represents a unique provider.	This is a value-added field created by Onpoint.	Unrestricted	X	
PC-PRV005	Prescribing Provider ID	This field contains an ID that identifies a unique combination of a provider's reported information.	This is a value-added field created by Onpoint.	Unavailable for abortions	X	
PC-PRV006	Prescribing Internal Provider ID	This field contains an ID that represents a unique provider.	This is a value-added field created by Onpoint.	Unavailable for abortions	X	
IPDIS801	Inpatient Discharge Record	This field contains an ID number that identifies a unique inpatient discharge record.	This is a value-added field created by Onpoint.	Unrestricted	X	

IPDIS803	Internal Member ID	This field contains an ID number that represents a unique member.	This is a value-added field created by Onpoint.	Restricted	(X)YES ()NO	This field can be used to aggregate all records associated with a member. We will need this variable to merge data files and create outcomes for our eligible population.
IPDIS804	Place of Setting	This field identifies the setting in which the care was rendered (e.g., hospital, swing bed, skilled nursing facility, etc.).	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS805	Date of Service (From)	This field identifies the first date of service for this service line.	This field is supplied as reported to Onpoint by the submitter using collection field (Date of Service (From)).	Restricted	(X)YES ()NO	We will need these variables to assign services to an episode of OUD treatment.
IPDIS806	Date of Service (Through)	This field identifies the last date of service for this service line.	This field is supplied as reported to Onpoint by the submitter using collection field (Date of Service (Through)).	Restricted	(X)YES ()NO	We will need these variables to assign services to an episode of OUD treatment.
IPDIS807	Admission Date	This field identifies the date of the inpatient admission.	This field is supplied as reported to Onpoint by the submitter using collection field (Admission Date).	Restricted	(X)YES ()NO	We will need these variables to assign services to an episode of OUD treatment.
IPDIS808	Discharge Date	This field identifies the discharge date of the patient from inpatient care.	This field is supplied as reported to Onpoint by the submitter using collection field (Discharge Date).	Restricted	(X)YES ()NO	We will need these variables to assign services to an episode of OUD treatment.
IPDIS810	Discharge Status Code	This field contains a code that identifies the status of the patient discharged from an inpatient stay.	This field is supplied as reported to Onpoint by the submitter using collection field (Discharge Status).	Unrestricted	X	
IPDIS811	Length of Stay	This field identifies the length of stay (in days) for an inpatient claim.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS812	Member Gender Code	This field contains a code that indicates the member's gender.	This field is supplied as reported to Onpoint by the submitter using collection field (Member Gender).	Unrestricted	X	
IPDIS813	Member Age (90+ Aggregate)	This field identifies the member's age in years.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS814	ICD Diagnosis Code – Admitting	This field contains the ICD diagnosis code used to report the member's diagnosis at the time of admission.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS815	ICD Diagnosis Code – Primary	This field contains the ICD diagnosis code used to report the member's primary diagnosis.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS816	ICD Diagnosis Code – 1	This field contains additionally reported ICD diagnosis code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS817	ICD Diagnosis Code – 2	This field contains additionally reported ICD diagnosis code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS818	ICD Diagnosis Code – 3	This field contains additionally reported ICD diagnosis code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS819	ICD Diagnosis Code – 4	This field contains additionally reported ICD diagnosis code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS820	ICD Diagnosis Code – 5	This field contains additionally reported ICD diagnosis code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS821	ICD Diagnosis Code – 6	This field contains additionally reported ICD diagnosis code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS822	ICD Diagnosis Code – 7	This field contains additionally reported ICD diagnosis code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS823	ICD Diagnosis Code – 8	This field contains additionally reported ICD diagnosis code.	This is a value-added field created by Onpoint.	Unrestricted	X	

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IPDIS850	ICD Procedure Code – 5	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS851	ICD Procedure Code – 6	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS852	ICD Procedure Code – 7	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS853	ICD Procedure Code – 8	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS854	ICD Procedure Code – 9	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS855	ICD Procedure Code – 10	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS856	ICD Procedure Code – 11	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS857	ICD Procedure Code – 12	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS858	ICD Procedure Code – 13	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS859	ICD Procedure Code – 14	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS860	ICD Procedure Code – 15	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS861	ICD Procedure Code – 16	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS862	ICD Procedure Code – 17	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS863	ICD Procedure Code – 18	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS864	ICD Procedure Code – 19	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS865	ICD Procedure Code – 20	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS866	ICD Procedure Code – 21	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS867	ICD Procedure Code – 22	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS868	ICD Procedure Code – 23	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS869	ICD Procedure Code – 24	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS870	ICD Procedure Code – 25	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS871	ICD Procedure Code – 26	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS872	ICD Procedure Code – 27	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS873	ICD Procedure Code – 28	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS874	ICD Procedure Code – 29	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	
IPDIS875	ICD Procedure Code – 30	This field contains an ICD procedure code.	This is a value-added field created by Onpoint.	Unrestricted	X	

IPDIS876	icd_version_ind	This field contains a code that identifies the version of ICD used to report this service line.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MH-CORE001	Medical Claim Header Record ID	This field contains an ID that identifies a unique claim.	This is a value-added field created by Onpoint.	Unrestricted	X	
MH-CORE003	Submitter ID	This field contains an ID that uniquely identifies a submitter.	This is a value-added field created by Onpoint.	Restricted	() YES (X) NO	
MH-CORE004	Internal Member ID	This field contains an ID that represents a unique member.	This is a value-added field created by Onpoint.	Restricted	(X) YES () NO	This field can be used to aggregate all records associated with a member. We will need this variable to merge data files and create outcomes for our eligible population.
MH-CORE005	Internal Provider ID	This field contains an ID that represents a unique provider.	This is a value-added field created by Onpoint.	Unavailable for abortions	X	
MH-CORE006	Member Age (90+ Aggregate)	This field identifies the member's age in years.	This is a value-added field created by Onpoint.	Unrestricted	X	
MH-CORE007	Date of Service (From)	This field identifies the first date of service for this service line.	This field is supplied as reported to Onpoint by the submitter.	Restricted	(X) YES () NO	We will need these variables to assign services to an episode of OUD treatment.
MH-CORE008	Date of Service (Through)	This field identifies the last date of service for this service line.	This field is supplied as reported to Onpoint by the submitter.	Restricted	(X) YES () NO	We will need these variables to assign services to an episode of OUD treatment.
MH-CORE009	First Paid Date	This field identifies the first payment date for the rendered service.	This is a value-added field created by Onpoint.	Unrestricted	X	
MH-CORE010	Last Paid Date	This field identifies the last payment date for the rendered service.	This is a value-added field created by Onpoint.	Unrestricted	X	
MH-CORE011	Charge Amount	This field identifies the total charges for the service.	This is a value-added field created by Onpoint.	Restricted	() YES (X) NO	
MH-CORE012	Paid Amount	This field identifies the total dollar amount paid to the provider, including all health plan payments and excluding all member payments and withholdings from providers.	This is a value-added field created by Onpoint.	Unrestricted	X	
MH-CORE013	Prepaid Amount	This field identifies the fee-for-service equivalent that would have been paid by the healthcare claims processor for a specific service if the service had not been capitated.	This is a value-added field created by Onpoint.	Unrestricted	X	
MH-CORE014	Copay Amount	This field identifies the preset, fixed dollar amount payable by a member, often on a per visit/service basis.	This is a value-added field created by Onpoint.	Unrestricted	X	
MH-CORE015	Coinsurance Amount	This field identifies the dollar amount that a member must pay toward the cost of a covered service, which is often a percentage of total cost.	This is a value-added field created by Onpoint.	Unrestricted	X	
MH-CORE016	Deductible Amount	This field identifies the dollar amount that a member must pay before the health plan benefits will begin to reimburse for services.	This is a value-added field created by Onpoint.	Unrestricted	X	
MH-CORE017	Allowed Amount	This field identifies the sum of the insurer and member paid dollar amounts	This is a value-added field created by Onpoint.	Unrestricted	X	
MH-CORE018	Insurer Paid Amount	This field identifies the sum of the insurer paid dollar amounts	This is a value-added field created by Onpoint.	Unrestricted	X	
MH-CORE020	ICD Diagnosis Code	This field contains a code that identifies the principal diagnosis.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	

MH-CORE021	ICD Version Indicator	This field contains a code that identifies the version of ICD used to report this service line.	This field is supplied as reported to Onpoint by the submitter using collection field (Principal Diagnosis ICD Version Indicator).	Unrestricted	X	
MH-CORE022	Claim Status Code	This field contains a code that identifies the status of the claim line - whether paid as primary, paid as secondary, denied, etc.	This is a value-added field created by Onpoint.	Unrestricted	X	
MH-CORE023	Denied Claim Flag	This field contains a flag that identifies a claim that was denied.	This is a value-added field created by Onpoint.	Unrestricted	X	
MH-CORE024	Orphaned Adjustment Flag	This field contains a flag that identifies a reported adjustment record for which the original claim was not submitted.	This is a value-added field created by Onpoint.	Unrestricted	X	
MH-CORE025	Claim Type ID	This field identifies an ID that identifies the type of claim (e.g., facility, professional, etc.) used to report this service line.	This is a value-added field created by Onpoint.	Unrestricted	X	
MH-CORE026	Type of Setting ID	This field provides additional granularity regarding the type of claim (e.g., inpatient, outpatient, provider, lab, etc.).	This is a value-added field created by Onpoint.	Unrestricted	X	
MH-CORE027	Place of Setting ID	This field identifies the setting in which the care was rendered (e.g., hospital, swing bed, skilled nursing facility, etc.).	This is a value-added field created by Onpoint.	Unrestricted	X	
MH-CORE028	Type of Bill Code	This field contains a code that identifies the reported type of bill.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
MH-CORE029	Emergency Room Flag	This field contains a code that is used to identify specific emergency room (ER) revenue or procedure codes within a claim.	This is a value-added field created by Onpoint.	Unrestricted	X	
MH-CORE030	Operating Room Flag	This field contains a code that is used to identify specific operating room (OR) revenue or procedure codes within a claim.	This is a value-added field created by Onpoint.	Unrestricted	X	
PRV-MAST001	Internal Provider ID	This field contains an ID that represents a unique provider.	This is a value-added field created by Onpoint.	Unrestricted	X	
PRV-MAST003	Entity Type	This field identifies whether the rendering provider was an individual or an organization.	This field is supplied as reported to Onpoint by the submitter.	Unrestricted	X	
PRV-MAST004	Organization Name	This field contains the name of the facility or organization associated with the reported service.		Unrestricted	X	
PRV-MAST005	Provider Last Name	This field contains the last name of the provider.	This field is supplied based on a crosswalk between submitter-supplied information and external sources (e.g., NPPES).	Unrestricted	X	
PRV-MAST006	Provider First Name	This field contains the first name of the provider.	This field is supplied based on a crosswalk between submitter-supplied information and external sources (e.g., NPPES).	Unrestricted	X	
PRV-MAST007	Provider Middle Initial/Name	This field contains the middle initial or name of the provider.	This field is supplied based on a crosswalk between submitter-supplied information and external sources (e.g., NPPES).	Unrestricted	X	

PRV-MAST008	Organization Name (Other)	This field contains an additional name of the facility or organization associated with the reported service.		Unrestricted	X	
PRV-MAST009	Organization Name (Other) Type	This field contains the type of the additional name of the facility or organization associated with the reported service.		Unrestricted	X	
PRV-MAST010	Provider Last Name (Other)	This field contains the other last name of the provider.	This field is supplied based on a crosswalk between submitter-supplied information and external sources (e.g., NPPES).	Unrestricted	X	
PRV-MAST011	Provider First Name (Other)	This field contains the other first name of the provider.	This field is supplied based on a crosswalk between submitter-supplied information and external sources (e.g., NPPES).	Unrestricted	X	
PRV-MAST012	Provider Middle Initial/Name (Other)	This field contains the other middle initial or name of the provider.	This field is supplied based on a crosswalk between submitter-supplied information and external sources (e.g., NPPES).	Unrestricted	X	
PRV-MAST013	Provider Suffix	This field contains the service provider's generational identifier (e.g., JR, SR, III).	This field is supplied based on a crosswalk between submitter-supplied information and external sources (e.g., NPPES).	Unrestricted	X	
PRV-MAST014	Provider Credential Code	This field contains the provider's credential code.	This field is supplied based on a crosswalk between submitter-supplied information and external sources (e.g., NPPES).	Unrestricted	X	
PRV-MAST015	Provider's Gender Code	This field contains the provider's gender.	This field is supplied based on a crosswalk between submitter-supplied information and external sources (e.g., NPPES).	Unrestricted	X	
PRV-MAST017	Provider NPI	This field contains the provider's National Provider Identification Number used by the U.S. Centers for Medicare & Medicaid Services (CMS).	This field is supplied based on a crosswalk between submitter-supplied information and external sources (e.g., NPPES).	Unrestricted	X	
PRV-MAST018	Provider's Primary Taxonomy	This field identifies the primary specialty as listed in the NPPES file for the provider.	This field is based on a combination of submitter-supplied information and external sources (e.g., NPPES).	Unrestricted	X	
PRV-MAST019	Provider's Secondary Taxonomy	This field identifies the secondary specialty as listed in the NPPES file for the provider.	This field is based on a combination of submitter-supplied information and external sources (e.g., NPPES).	Unrestricted	X	
PRV-MAST029	Provider Physical City	This field identifies the city for the reported provider location.	This field is supplied based on a crosswalk between submitter-supplied information and external sources (e.g., NPPES).	Unrestricted	X	
PRV-MAST030	Provider Physical State or Province	This field identifies the state or province of the provider's physical location using the two-character abbreviation defined by the U.S. Postal Service (for U.S. states) and Canada Post (for Canadian provinces).	This field is supplied based on a crosswalk between submitter-supplied information and external sources (e.g., NPPES).	Unrestricted	X	

PRV-MAST031	Provider Physical ZIP/Postal Code	This field identifies the ZIP/postal code for the reported provider location.	This field is supplied based on a crosswalk between submitter-supplied information and external sources (e.g., NPPEs).	Unrestricted	X	
PRV-MAST032	Provider Physical Country	This field identifies the country for the reported provider location.	This field is supplied based on a crosswalk between submitter-supplied information and external sources (e.g., NPPEs).	Unrestricted	X	

¹ Data coded as "Restricted" are categorized as such under VHCURES Rule H-2008-01. Applicants must describe how restricted data support the research purpose of the project described in the DUA application. Data coded as "Unrestricted" are available for general or public use. Many are value-added elements that facilitate use of the data set.

² Health care provider data elements are not released if the medical claim record is flagged as a medical abortion or the pharmacy claim record is flagged as a medication abortion.



Office of Research Protection

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EXEMPT DETERMINATION

April 16, 2018

Susan Haber

781-434-1721, x21721
shaber@rti.org

Dear Susan Haber:

On 4/16/2018, the IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Treatment and Outcomes for Patients with Opioid Use Disorder after Cessation of Opioid Prescription
Investigator:	Susan Haber
IRB ID:	STUDY00020119
Funding Source:	RTI
Customer/Client Name:	Unassigned Customer
Project/Proposal Number:	0271800.052
IND, IDE, or HDE:	None

The IRB determined that this study meets the criteria for exemption from IRB review. In conducting this study, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the IRB system.

Ongoing IRB review and approval by this organization is not required. This determination applies only to the activities described in the IRB submission and may not apply should any changes be made. If changes are made and there are questions about whether these activities impact the exempt determination, you should contact the IRB to discuss whether a new submission and determination is necessary.

Sincerely,

The RTI Office of Research Protection